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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,692	09/14/2005	Annick Harel-Bellan	BDM-05-1130	9223
35811 7590 12/13/2007 IP GROUP OF DLA PIPER US LLP ONE LIBERTY PLACE 1650 MARKET ST, SUITE 4900 PHILADELPHIA, PA 19103			EXAMINER ZARA, JANE J	
			ART UNIT 1635	PAPER NUMBER
			MAIL DATE 12/13/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/535,692

Applicant(s)

HAREL-BELLAN ET AL.

Examiner

Jane Zara

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 17, 19 and 21-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17, 19 and 21-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 5-19-05.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

This Office action is in response to the communication filed 10-12-07.

Claims 17, 19, 21-27 are pending in the instant application.

***Election/Restrictions***

Claims 1-16, 18 and 20 have been withdrawn (and have been canceled) from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10-12-07.

Applicant's election without traverse of Group II, claims 17 and 19 in the reply filed on 10-12-07 is acknowledged. Claims 21-27, pertaining to original claims 10-16 have been rejoined since they, along with original claims 17 and 19, comprise a product and process of use of said product under 37 CFR 1.475(b).

***Claim Objections***

Claim 21 is objected to because of the following informalities: In line 5 of claim 21, "a lox sit" is claimed. It appears that "sit" should be replaced with --site.--. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 27 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method comprising transfecting a cell with a molecule of nucleic acid comprising a regulating sequence and the cre gene.

The specification, claims and the art do not adequately describe the distinguishing features or attributes concisely shared by the members of the genus encompassing a regulating sequence. The specification teaches nucleic acid constructs comprising inducible and constitutive promoters. The genus of compounds claimed, however, encompasses numerous structures, encompassing any regulating sequence, which includes enhancers, repressors, promoters, etc.

The specification, claims and art do not adequately teach a representative number of species for the broad genus claimed, encompassing any regulating sequence. Concise structural features that could distinguish structures within the genus from others are missing from the disclosure, whereby a representative number of species is particularly described which provides for the function claimed, of regulating gene expression. For these reasons, the instant disclosure fails to provide adequate written description for the genus of nucleic acids claimed.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 17, 19, 21-25 and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Taira et al (US 2004/0002077).

Taira et al (US 2004/0002077) teach compounds and methods of expressing RNAi in cells comprising introducing a nucleic acid molecule into a eukaryotic cell, which nucleic acid molecule comprises a sense and antisense sequence under control of a promoter for single transcription, which sequences are separated by a stop codon or optionally comprising an antibiotic resistant gene, and which nucleic acid sequence is flanked by lox sites, whereby upon recombination under appropriately inducible conditions and in the presence of Cre expression, RNAi is formed in the cell (see abstract, paragraphs 0023-0044, figures 1, 3-7, 10, paragraphs 0117-0119, 0126, claims 14, 17, 18, 22, 25-27).

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17, 19 and 21-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taira et al (US 2004/0002077) as applied to claims 17, 19, 21-25 and 27 above, and further in view of Srivastava (USPN 5,948,646).

Taira et al (US 2004/0002077) is relied upon as cited in the 102 rejection above. Taira does not teach the transcription terminator to be the neomycin resistant gene.

Srivastava (USPN 5,948,646) teach the use of antibiotic resistant genes in expression plasmids, including hygromycin and neomycin resistant genes, to enhance selection of cells containing these antibiotic resistant selection markers (e.g. to select away from untransfected cells) (see bridging paragraph, col. 16-17).

It would have been obvious to one of ordinary skill in the art to design and synthesize nucleic acid molecules for methods of expressing RNAi in cells comprising introducing a nucleic acid molecule comprising a sense and antisense sequence under

control of a promoter, which sense and antisense sequences are separated by a stop codon or optionally comprising an antibiotic resistant gene, and which nucleic acid sequence is flanked by lox sites, whereby upon recombination under appropriately inducible conditions and in the presence of Cre expression, RNAi is formed in the cell because this method and constructs for doing so were taught previously by Taira. One would have been motivated to insert a neomycin resistant gene into this construct, including as an intervening gene between the sense and antisense sequences in order to determine the level of transfection of the nucleic acid construct in a target cell prior to recombination. One of ordinary skill in the art would have expected that, prior to recombination, cells comprising this construct would be selected in the presence of neomycin, therefore enriching transfected cell populations. One of ordinary skill in the art would have been motivated to devise such a construct so that, upon recombination, an SiRNA construct would be formed for target gene inhibition. One of ordinary skill in the art would have expected that homologous recombination in the presence of Cre expression, SiRNA would form and target gene inhibition occurs.

For these reasons, the instant invention would have been obvious to one of ordinary skill in the art at the time the instant invention was made.

### ***Conclusion***

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. ' 1.6(d)). The official fax telephone number for the

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Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jane Zara whose telephone number is (571) 272-0765. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz, can be reached on (571) 272-0763. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jane Zara  
12-11-07

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PRIMARY EXAMINER